UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,907	09/18/2001	Jean-Claude Beauvillain	208888USOPCT	3062

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EXAMINER
SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Advisory Action	**Application No.**	**Applicant(s)**
	09/831,907	BEAUVILLAIN ET AL.
	Examiner	**Art Unit**	
	Daniel M Sullivan	1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may <u>only</u> be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

<u>PERIOD FOR REPLY</u> [check either a) or b)]

a) ☒ The period for reply expires <u>3</u> months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____ . Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

    (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

    (b) ☐ they raise the issue of new matter (see Note below);

    (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

    (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
        NOTE: _____ .

3.☒ Applicant's reply has overcome the following rejection(s): <u>See Continuation Sheet</u>.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

    The status of the claim(s) is (or will be) as follows:

    Claim(s) allowed: _____ .

    Claim(s) objected to: *16 and 17*.

    Claim(s) rejected: *1,9,10,14 and 15*.

    Claim(s) withdrawn from consideration: *3-8,11-13*.

8.☒ The drawing correction filed on *02 January 2004* is a)☒ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____ .

10.☐ Other: _____ .

PRIMARY EXAMINER

Continuation of 3. Applicant's reply has overcome the following rejection(s): Rejection of claim 14 stands 35 U.S.C. 112, second paragraph, as indefinite.

Continuation of 5. does NOT place the application in condition for allowance because: Claims 9 and 10 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the Remarks, Applicant urges that the rejection is completely without merit because the skilled artisan would possess sufficient abilities on the basis of the present disclosure and the skill generally available in the art to admix the inventive polypeptides with a pharmaceutically acceptable vehicle without undue experimentation. This argument has been fully considered but is not deemed persuasive. Applicant asserts that the enabling disclosure must teach the skilled artisan how to make "or" use the invention (page 10, emphasis added). However, the first paragraph of 35 U.S.C. §112 actually states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make 'and' use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." (emphasis added). Thus, the enabling disclosure must teach how to use, as well as make, a claimed composition. The Office interprets claims directed to "pharmaceutical compositions" as compositions to be used as pharmaceuticals. Therefore, the enabling disclosure must teach the skilled artisan how to use the composition therapeutically. For reasons of record, the specification does not provide teachings that would enable the skilled artisan to use the disclosed polypeptides as pharmaceuticals. Therefore, claims to pharmaceutical compositions, or methods of making pharmaceutical compositions, are not enabled because the skilled artisan would not be able to use the claimed invention without first engaging in undue experimentation. It is noted that claims to the composition and method of making the composition would be enabled if they were not limited to being pharmaceutical.

Claims 1, 9, 10, 14 and 15 stand rejected under 35 U.S.C. 102(e) as being anticipated by Culp et al. U.S. Patent No. 6,075,137. Applicant has amended the claims such that they are no longer directed to a polypeptide selected from the human sequence 3 and argues that Culp et al. does not anticipate the sequence set forth as SEQ ID NO: 2 because, "the present claims are specifically drawn to the polypeptide of SEQ ID NO: 2 and not long polypeptides that happen to have a stretch that is identical to the claimed sequence" (page 9). However, the Office interprets any claim to an amino acid sequence not explicitly limited to "consisting of" the disclosed sequence as reading on any sequence comprising the disclosed sequence. In the instant claims, the phrase "consisting of" appears to be referring to the Markush group and does not limit the sequences within that group to consisting of the named sequences. Therefore, to the extent that the sequence disclosed in Culp et al. comprises SEQ ID NO: 2, the claims are anticipated by the prior art.

Please note: The previous Office Action states, "[t]his application contains claims 3-8 and 11-13 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01" (page 2). A response to the present Office Action that does not address the non-elected subject matter will be deemed nonresponsive..